

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

SCIELE PHARMA, INC.,	)	
ANDRX CORPORATION, ANDRX	)	
PHARMACEUTICALS, INC. (N/K/A	)	
WATSON LABORATORIES, INC.-	)	
FLORIDA), ANDRX PHARMACEUTICALS,	)	C.A. No. 09-037 (RBK)(JS)
L.L.C., ANDRX LABORATORIES (NJ),	)	CONSOLIDATED
INC., ANDRX EU LTD., AND ANDRX	)	
LABS, L.L.C.,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	
	)	
LUPIN LTD., and	)	
LUPIN PHARMACEUTICALS, INC.,	)	
	)	
Defendants.	)	

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SHIONOGI, INC.,	)	
ANDRX CORPORATION, ANDRX	)	
PHARMACEUTICALS, INC. (N/K/A	)	
WATSON LABORATORIES, INC.-	)	
FLORIDA), ANDRX PHARMACEUTICALS,	)	
L.L.C., ANDRX LABORATORIES (NJ),	)	
INC., ANDRX EU LTD., AND ANDRX	)	
LABS, L.L.C.,	)	C.A. No. 10-135 (RBK)(JS)
	)	
Plaintiffs,	)	
	)	
v.	)	
	)	
MYLAN, INC., and	)	
MYLAN PHARMACEUTICALS INC.,	)	
	)	
Defendants.	)	

**PLAINTIFFS' AMENDED NOTICE OF**  
**30(b)(6) DEPOSITION OF THE MYLAN DEFENDANTS**

PLEASE TAKE NOTICE that Plaintiff Sciele Pharma, Inc., n/k/a Shionogi Inc., ("Shionogi") and Plaintiffs Andrx Corporation, Andrx Pharmaceuticals, Inc., n/k/a Watson

Laboratories, Inc. - Florida, Andrx Pharmaceuticals, L.L.C., Andrx Laboratories (NJ), Inc., Andrx EU Ltd., and Andrx Labs, L.L.C. (“Andrx”) (collectively “Plaintiffs”) will take the deposition by oral examination of Defendants Mylan Inc. and Mylan Pharmaceuticals Inc. (collectively “Mylan”) pursuant to Rule 30(b)(6) of the Federal Rules of Civil Procedure. The deposition will take place at the offices of WilmerHale, 399 Park Avenue, New York, New York 10022, beginning at 9:30 a.m. on April 3, 2012, or at another agreed upon date and time, and will continue thereafter day to day until completed. The topics of the deposition are set forth in Schedule A.

Pursuant to Rule 30(b)(6), Mylan is required to designate one or more officers, directors, employees or other persons who will testify on its behalf regarding the topics listed in Schedule A. Mylan is requested to provide Plaintiffs’ counsel, as soon as reasonably possible, but no later than 10 business days before the deposition, a written designation of the name(s) and position(s) of the agent(s) or other person(s) who will be produced to testify on behalf of Mylan and, for each person designated, the topics set forth in the attached Schedule A as to which he or she will testify.

The deposition will be taken before a qualified Notary Public or before some other officer authorized by law to administer oaths. The deposition will be recorded by video and stenographic means. You are invited to attend and cross-examine.

RICHARDS, LAYTON & FINGER P.A.

*/s/ Jason J. Rawnsley*

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February 7, 2012

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

*/s/ Julia Heaney*

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## **SCHEDULE A**

### **DEFINITIONS**

1. Any reference to a business entity includes all entities and persons acting on the business entity's behalf as well as all affiliates, divisions, parents, subsidiaries, and predecessors and successors thereof.

2. Any term defined in the singular also includes the plural and vice versa.

3. The terms "and" and "or" shall be interpreted liberally as conjunctive, disjunctive, or both so that the fullest disclosure of information is achieved.

4. The term "ANDA" means Abbreviated New Drug Application.

5. The term "communication" refers to all conversations, agreements, inquiries, or replies, whether in person, by telephone, in writing, or by means of electronic transmittal devices, and includes, but is not limited to, all correspondence, transmittal slips, memoranda, or notes.

6. The term "concerning" means in any way, directly or indirectly, regarding, considering, constituting, covering, defining, describing, involving, underlying, modifying, amending, confirming, mentioning, endorsing, recording, evidencing, pertaining to, referring to, reflecting, relating to, representing, supporting, qualifying, terminating, revoking, canceling, negating, or having any connection with the matter discussed.

7. The term "document" means each and every writing, whether an original, a draft, or a copy, however produced or reproduced, and each and every thing from which information can be processed or transcribed, and includes, without limitation, all things meeting the definitions of "writings" and "recordings" as set forth in Fed. R. Evid. 1001. Any document without any marks such as initials, comments, or notations of any kind is not deemed to be

identical to one without such marks and is to be produced and identified as a separate document. The term “document” is coextensive in scope with Rule 34 of the Federal Rules of Civil Procedure.

8. The term “drug product” has the meaning set forth in 35 U.S.C. § 156(f)(2).

9. The term “Extended Release Metformin Product” means any extended release drug product that includes metformin or a salt thereof as its active ingredient, regardless of the name or designation used in a particular document or thing.

10. The term “FDA” means the United States Food and Drug Administration.

11. The term “FORTAMET®” means the metformin hydrochloride product sold in the United States under approved New Drug Application No. 21-574.

12. The term “Matrix” means Matrix Laboratories Ltd., and each of their respective officers, directors, representatives, employees, agents, partners, corporate parents, subsidiaries, affiliates, predecessors, and successors.

13. The term “Mylan” means Mylan Inc., and Mylan Pharmaceuticals, Inc., and each of their respective officers, directors, representatives, employees, agents, partners, corporate parents, subsidiaries, affiliates, predecessors, and successors, including but not limited to Matrix Laboratories Ltd. (“Matrix”).

14. As used herein, “Mylan’s ANDA” means ANDA No. 200690.

15. As used herein, “Mylan’s ANDA Metformin Products” means the metformin products that are the subject of Mylan’s ANDA.

16. The term “Mylan’s Paragraph IV Certification” means the patent certification filed by Mylan with the FDA pursuant to section 505(j)(2)(B) of the Federal Food, Drug and Cosmetic Act and § 314.95 of Title 21 of the Code of Federal Regulations in support of its

ANDA with respect to metformin hydrochloride extended-release tablets USP, 500 mg and 1000 mg, as referenced in the Notice Letter.

17. The term “Notice Letter” means the letter dated January 4, 2010 from Mylan Pharmaceuticals Inc. to Andrx, regarding “Paragraph IV Patent Certification Notice – U.S. Patents [sic] Nos. 6,099,859, 6,495,162, 6,790,459, and 6,866,866 Metformin Hydrochloride Extended-Release Tablets USP, 500 mg and 1000 mg Mylan Pharmaceuticals Inc.’s ANDA No. 200690.”

18. The term “person” or “persons” means any natural person or business, legal, or governmental entity or association.

19. The term “patents-in-suit” refers to U.S. Patent Nos. 6,099,859 (the “859 Patent”) and 6,866,866 (the “866 Patent”).

### **TOPICS OF EXAMINATION**

1. The decision by Mylan to develop an Extended Release Metformin Product, including the Mylan’s ANDA Metformin Products, or any other metformin product that might be A/B rated to FORTAMET®.

2. The research and development of or leading to Mylan’s ANDA Metformin Products, including but not limited to Mylan’s research and development of Extended Release Metformin Products for which Mylan did not submit in an ANDA or which did not show bioequivalence to FORTAMET®, and the identities and respective responsibilities or contributions of individuals involved in that research and development, whether employees of Mylan, subsidiaries of Mylan such as but not limited to Matrix, or third parties.

3. The composition and/or formulation of each of the Mylan’s ANDA Metformin Products, including but not limited to their chemistry, pharmacokinetics, and dissolution profile.

4. The use and/or intended use of each of the Mylan's ANDA Metformin Products.

5. The research, design, and development leading to, and production of the Mylan's ANDA Metformin Products, including without limitation any research and development relating to metformin, any research and development relating to FORTAMET®, any research and development relating to generic versions of FORTAMET®, any research and development relating to alternatives to FORTAMET®, and the amount of money and time invested by Mylan in the research, design, and development of the Mylan's ANDA Metformin Products.

6. The portions of Mylan's ANDA relating to chemistry, formulation, manufacturing, pharmacokinetics or labeling, and, any amendments or supplements thereto, including but not limited to their preparation, any correspondence or communications between Mylan and the FDA concerning these portions of Mylan's ANDA, any correspondence or communications between Mylan and Matrix or any other Mylan subsidiary concerning these portions of Mylan's ANDA, any internal Mylan documents or communications concerning these portions of Mylan's ANDA, and the content of Mylan's ANDA.

7. The preparation and filing of Mylan's ANDA, including without limitation, all tests, analyses, studies, information, evaluations, and data contained or referenced in Mylan's ANDA, and/or relied upon by Mylan in preparing Mylan's ANDA, the decision to prepare and file Mylan's ANDA, any plans to supplement Mylan's ANDA, and the amount of money and time invested by Mylan in the preparation and filing of Mylan's ANDA.

8. Any consideration or analysis by Mylan of the commercial success of FORTAMET® or a generic Extended Release Metformin Product, including the sales or potential sales of such products by Mylan or other companies.

9. In vitro and in vivo testing relating to the formulation or pharmacokinetics of Mylan's Metformin ANDA Products, including components thereof, the identities and respective responsibilities of all individuals having a role in the analytical testing of Mylan's ANDA Metformin Products whether employees of Mylan, subsidiaries including but not limited to Matrix, or third parties.

10. Any clinical or preclinical testing concerning the dissolution profile and/or pharmacokinetic properties of Mylan's ANDA Metformin Products, including but not limited to the identities and respective responsibilities of all individuals having a role in the testing of Mylan's ANDA Metformin Products whether employees of Mylan, subsidiaries including but not limited to Matrix, or third parties.

11. Mylan's proposed or potential labeling for Mylan's ANDA Metformin Products, including communications concerning the content of the labeling and any related documents, and the identities of individuals, whether employees of Mylan, subsidiaries including but not limited to Matrix, or third parties, having a role in the labeling.

12. Any studies, tests, analyses, investigations, and/or evaluations done by or on behalf of or known to Mylan concerning the actual or potential market for Extended Release Metformin Products, the clinical needs met by Extended Release Metformin Products, and the commercial success of FORTAMET®.

13. Mylan's proposed or actual marketing, distribution, and sales of an Extended Release Metformin Product, including analysis of the actual or potential market for FORTAMET® or Mylan's ANDA Metformin Products, Mylan's actual or contemplated plans and strategy to sell or market Mylan's ANDA Metformin Products, and any sales or market share projections or analyses for FORTAMET® or Mylan's ANDA Metformin Products, any studies,



tests, analyses, investigations, and/or evaluations done by or on behalf of or known to Mylan concerning the clinical needs met by Extended Release Metformin Products, and the commercial success of FORTAMET®, including the identities of individuals with responsibilities for the proposed marketing, distribution, and sales of the product whether employees of Mylan, subsidiaries including but not limited to Matrix, or third parties.

14. Mylan's domestic forecasting, budgeting, and financial or strategic planning relating to Mylan's ANDA Metformin Products, including any evaluations or criteria of profitability, profit studies, return-on-investment analyses, or pricing guidelines and including sales, market, budget, cost, margin or revenue forecasts or projections, business plans, marketing plans, consultant reports, or strategy or competitive analyses.

15. The benefits, including revenues and profits, that Mylan projects or plans to obtain should Mylan's ANDA be approved by the U.S. Food and Drug Administration.

16. Knowledge, notice, and/or consideration by Mylan of the '859 and/or '866 Patents prior to the filing of Mylan's ANDA, including without limitation, the person(s) at Mylan who first learned of the '859 and/or '866 Patents, the circumstances through which they first learned of the '859 and/or '866 patents.

17. Any patent policy in effect at Mylan at any time since 2005.

18. Any research or analysis performed by Mylan regarding the '859 and/or '866 Patents prior to the filing of Mylan's ANDA, including but not limited to, any efforts to compare Mylan's ANDA Metformin Products to the '859 and/or '866 Patents and all documents or any other evidence that Mylan considered in determining that the Mylan's ANDA Metformin Products when marketed will not infringe one or more of the asserted claims of the '859 and/or '866 Patents.

19. All market projections and launch plans for Mylan's ANDA Metformin Products.

20. Any and all prior art searches, investigations, or analyses and results thereof, conducted or obtained by Mylan or on its behalf, relating to the validity, enforceability, enforcement, or claim construction of the '859 and/or '866 Patents, including without limitation the identity of any persons involved in, and any documents relating to, any such searches, investigations, or analyses.

21. All information relating to opinions of counsel, whether oral or in writing, concerning the '859 and/or '866 Patents, including when such opinion was requested, why such opinion was requested, from whom such opinion was requested, when it was received, by whom it was received, by whom it was evaluated, and who, if anyone, relied upon any such opinion.

22. Any licensing, supply, shipping, or other contractual agreement or understanding between Mylan and any other person or entity concerning Mylan's ANDA Metformin Products.

23. The preparation of Mylan's January 4, 2010 Paragraph IV Notice Letter to Andrx.

24. Mylan's corporate organizational structure, including, but not limited to, the organizational structure of the business unit(s) (however designated) responsible for the conception, design, operation, function(s), research and development, manufacturing, sales and licensing, and/or marketing and advertising of Mylan's ANDA Metformin Products, the identification of its board of directors and corporate officers, and those of its affiliates and subsidiaries such as but not limited to Matrix.

25. All documents produced by, and discovery responses served by, Mylan in connection with this lawsuit.

26. The locations and custodians of documents relevant to the Topics of this Rule 30(b)(6) deposition notice.

27. The methodology, procedure, and efforts made by Mylan to identify, search for, locate, gather and produce documents responsive to Shionogi's discovery requests, including the identities of persons who were contacted to identify, search for, locate, and gather documents, the locations that were searched, and the location and custodians of the documents that were produced.

28. All steps taken by each person designated to testify about any of the matters set forth above to acquire all information known or reasonably available to Mylan about each such matter, including all documents reviewed, discussed or prepared in connection with or in anticipation of the testimony by each designated witness, all communications with any person who provided any information about which testimony is provided or sought, and the identities of any individual(s) consulted to obtain information about which testimony is provided or sought.

29. Mylan's document retention or destruction policies in effect at any time since 2005.

**CERTIFICATE OF SERVICE**

I hereby certify that on February 7, 2012, I electronically filed the foregoing with the Clerk of the Court using CM/ECF, which will send notification of such filing(s) to the following all registered participants.

I also certify that copies were caused to be served on February 7, 2012, upon the following in the manner indicated:

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*/s/ Julia Heaney*

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